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APPLICATION NO. 09/066,255	FILING DATE 04/24/98	FIRST NAMED INVENTOR BUECHLER	K	ATTORNEY DOCKET NO. 554718
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ART UNIT

PAPER NUMBER

02/01/00 6

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/066,255

Applicant(s)

Buechler et al

Examiner

Maurie E. Garcia, Ph. D.

Group Art Unit

1627



☒ Responsive to communication(s) filed on Nov 29, 1999

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire THREE month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 23-35 is/are pending in the application

Of the above, claim(s) 23-27, 29, 31, 33, and 35 is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 28, 30, 32, and 34 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

DETAILED ACTION

Please note: the number of Art Unit 1618 has been changed to 1627. Please direct all correspondence for this case to **Art Unit 1627**.

1. The response filed November 29, 1999 is acknowledged. Claims 28 and 29 were amended and claims 30-35 were added. Currently, claims 23-35 are pending.

Election/Restriction

2. Applicant's election with traverse of Group II (Claim 28) in Paper No. 5 is acknowledged. The new claims fall within the previous groups as follows:

Group II: Claims 28, 30, 32, 34; Group III: Claims 29, 31, 33, 35.

The traversal is made between Groups II and III and is on the ground(s) that there is a lack of burden. This is not found persuasive because of the following reasons.

3. In the instant case, Groups II and III are different methods and differ in their steps and the reagents required for each. Group II is a competitive method, while Group III is a non-competitive method. Group II requires a ligand analogue and Group III does not. Furthermore, it is the ligand analogue that is conjugated to the phthalocyanine derivative in Group II, and the receptor is free in solution. In Group III, the ligand receptor is conjugated to the phthalocyanine derivative. These are completely different reagents with different structures.

4. These inventions have acquired a separate status in the art as shown by their divergent subject matter. Please note that even though these methods could be classified in the same class/subclass, this has no effect on the non-patent literature search. The different methods would require completely different searches in these databases, and there is no expectation that the searches would be coextensive. Therefore, this does create an undue search burden, and restriction for examination purposes as indicated is proper.

5. The restriction requirement is therefore made FINAL. Claims 28, 30, 32, 34 are examined and claims 23-27, 29, 31, 33 and 35 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to non-elected inventions.

Drawings

6. This application has been filed with informal drawings which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed. These drawings will be reviewed by the draftsman and a PTO-948 will be sent to applicant in due course.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a

person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 30 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Renzoni et al (US 5,135,717) in view of Freytag (US 4,434,236).

Renzoni et al teach water-soluble phthalocyanine derivatives (see column 3, lines 29-55) that read directly on those of the instant claims. These phthalocyanines are conjugated to biologically active agents such as antibodies (column 39, lines 1-25), peptides or nucleotides (see claim 3 of the reference). The conjugates can be used in biological assays (see Example 16, column 39). The Renzoni reference lacks the specific teaching of a competitive assay as recited in the claims.

However, one of ordinary skill in the art would know that such labeled antibodies could be used in a competitive assay, because such assays were very well known in the art at the time of filing. For example, Freytag teaches an assay that is the same as the one claimed, except for the fact that Freytag uses different labels for the antibodies than the

ones of the instant claims (see Abstract, Examples and claims 1-7 of the reference).

However, Freytag does discuss that fluorophores can be used for labeling the antibodies (column 3, lines 43-48).

Therefore it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to use the water-soluble phthalocyanine derivatives of Renzoni et al as the fluorescent tags in the method of Freytag. A person of ordinary skill in the art would have been motivated to make such a substitution to use a fluorophore with "more ideal spectral properties" as taught by Renzoni et al (column 1, lines 49-52).

10. Claims 28 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Renzoni et al (US 5,135,717) in view of Freytag (US 4,434,236) as applied to claims 30 and 34 above, and further in view of Stanton et al (US 4,803,170).

The combination of Renzoni et al and Freytag teach that water-soluble phthalocyanine derivatives can be used in a competitive assay, as discussed *supra*. Neither of the references discloses the configuration of bound ligand analogue in step b (claim 28) and furthermore the prior binding to a solid phase (claim 32) recited in the instant claims.

However, one of ordinary skill in the art would know that such a configuration could be easily achieved, and would simply be a design choice in the creation of the assay set-up. Such assays were well known in the art at the time of filing. For example,

Stanton et al discusses a competitive assay where the analyte conjugate and ligand/marker binding partner are both bound to a solid phase (Abstract and column 3). Most importantly, "excess analyte conjugate becomes sequestered...on a surface, where its marker activity can be read as an indication of analyte presence" (column 3, line 66 – column 4, line 1).

Therefore it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to use the water-soluble phthalocyanine derivatives of Renzoni et al as the fluorescent tags in the method of Freytag and to furthermore use the bound configuration of Stanton et al. A person of ordinary skill in the art would have been motivated to make such a substitution to create a more facile assay, as taught by Stanton et al (column 1, lines 9-18).

Status of Claims/ Conclusion


11. No claims are allowed.
12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maurie E. Garcia, Ph.D. whose telephone number is (703) 308-0065. The examiner can normally be reached on Monday-Thursday and alternate Fridays from 8:30 to 6:00.
13. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Donald E. Adams, Ph.D., can be reached on (703) 308-0570. The fax phone number

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for the organization where this application or proceeding is assigned is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Maurie E. Garcia, Ph.D.
January 31, 2000


Keith MacMillan
Primary Examiner
AU 1627